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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,593	08/29/2001	Masaharu Nishida	NIP-243	5020

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EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/940,593

Applicant(s)

NISHIDA ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 August 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The following is the response to the amendment filed on 08/11/04. Claims 1-9 are cancelled. Claims 10-15 are pending in the application.

### ***Election/Restrictions***

2. Newly submitted claims 13-15 (with claim 15 obviously having an error of reciting "a reagent setup method" instead of "apparatus") are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to a reagent setup apparatus, which is classified in a different class and requires a separate search. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Drawings***

3. Figure 2 is still unclear. Left side of the drawing refers to three different companies, having different sets of reagents. The right side of the drawing at the same time refers to just one company A with the same sets of reagents, as the left side of the drawing. This makes it very confusing, of what is represented on the drawing.

### ***Specification***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The specification is objected to as not being written “in such full, clear, concise, and exact terms as to enable any person skilled in the art” to practice the invention in its best mode. For example, it is not clear, what does the expression “parameters on the required reagents ... are to be registered on an inspection item basis” means. What is the “inspection item basis” in the present context? Does it mean that the parameters are registered to be compared for inspection? What are “batch-registered reagent-dependent parameters corresponding to the particular specification of the analytical apparatus” (page 4, lines 23-24)? What type of parameter batches are disclosed? Of different reagents from the same company? Of the same reagent from different companies? The batches defined by the tests? Further, the registration is supposedly conducted for the reagents. But on page 8, lines 13-16 the specification discloses, “the registration is conducted for either the analytical apparatus of the corresponding analytical apparatus manufacturer before the apparatus is delivered, or the analytical apparatus that was delivered to the user”. Therefore, the specification discloses a plurality of reagents, a plurality of reagent manufacturers, and a plurality of analytical apparatus manufacturers. It is hard to understand connections between these pluralities. Moreover, from Figure 2 it is not clear, first, how the information for the reagents from company A becomes the one for company B? If it is an error of the drawing, and three floppy disks are supposed to correspond companies A, B and C, then it is not clear, where is the information regarding items 2 and 4-5 of company A, items 1, and 3-4 of company B, and items 1, 6, 9 of company C gone? Is it stored somewhere separately? The disclosure is completely confusing. If the specification was meant to disclose redistributing information about various reagents supplied by different manufacturers so that the information on the same reagent from different manufacturers were stored in the same place with the similar analytical tests to be performed for this reagent on the analytical instrument for its start-up, it failed to do so. If it meant to disclose something else, the examiner did not get any idea on what the subject matter of the specification should have been in this case.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is not clear as to what is a “reagent parameter set corresponding to specifications of said reagents”? Is this just one set of reagent parameters for all reagents produced by plurality of manufacturers? Are these different parameters for different reagents and for different manufacturers? It is not clear, what just one set of reagent parameters might be. Also, are there different specifications for different reagents produced by different manufacturers, and if there are, how can be just one reagent parameter set for all these specifications?

Claim 11 is not clear as to what is “measuring a series of data of samples .... by using said reagent supplied by said plural reagent manufacturers”. First, it is not clear, if there is a typo in the word “reagent” vs. “reagents” recited in the parent claim. Second, it is not apparent of how the “series of data” can be measured by using multiple reagents supplied by multiple manufacturers? Is it supposed to be a measurement for the same analyte but with a plurality of different reagents? This does not make much sense. The subject matter pf claim 11 is not clear.

Claim 12 is not clear, as to how it further limits claim 11; measuring the series of data of the samples inherently comprises reporting the results in various formats, including graphical representation. It is not clear, what further limitation to the parent claim is supposed to be recited in claim 12.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. **Claims 10-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 2002/0143725 A1).

Smith discloses "systems, methods and computer program products for determining parameters for chemical synthesis and for supplying the reagents, equipment and/or chemicals synthesized thereby" (Abstract). "As also shown in FIGS. 1E-1G, data entry 110, user query 120 and transactions 130 may be used separately according to embodiments of the present invention. Thus, in FIG. 1E, data entry 110 may be used to populate a database of a plurality of target chemicals, a plurality of corresponding listings of reagent chemicals, a plurality of corresponding listings of equipment and a plurality of corresponding listings of procedures. This database may include three related databases: a chemical database, an equipment database and a supplier database. As part of data entry, a plurality of target chemicals, a plurality of first pointers to a corresponding plurality of listings of reagent chemicals in the chemical database, a plurality of second pointers to a corresponding plurality of listings of equipment in the equipment database, and a plurality of corresponding listings of procedures are entered into the chemical database.

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The plurality of listings of equipment are entered into the equipment database, along with a plurality of third pointers to a corresponding plurality of listings of equipment suppliers in the supplier database" (col. 3, [0030]).

While Smith does not specifically disclose parameters on reagents from different suppliers, it would have been obvious for anyone of ordinary skill in the art to include such information in the database, i.e. to register reagents from different suppliers, in order to optimize the choice for their further usage.

### ***Response to Arguments***

11. Applicant's arguments filed 08/11/04 have been fully considered but they are not persuasive. The specification is written in such an unclear and indefinite language that its interpretation is ambiguous. Since the explanation of the invention in the Applicants' remarks seems to indicate a registration of reagents from different companies, with their parameters to be retrieved for performing analysis (before? during? after?), this subject matter reads on the prior art of Smith, as demonstrated above.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh  
10/29/04

